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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,403	06/04/2001	Pramod K. Srivastava	8449-178-999	1802

20583 7590 11/03/2006

JONES DAY  
222 EAST 41ST ST  
NEW YORK, NY 10017

EXAMINER
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YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/873,403	<b>Applicant(s)</b> SRIVASTAVA ET AL.	
	<b>Examiner</b> Christopher H. Yaen	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,7-9,40 and 42-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 43-49 and 58-60 is/are allowed.
- 6) ☒ Claim(s) 1,7,9,11,40,42,50-57 and 61-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/14/2006</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

**Re: SRIVASTAVA *ET AL***

The amendment filed 8/14/2006 is acknowledged and entered into the record.

Accordingly, claims 2-6,10-39, and 41 are canceled without prejudice or disclaimer, and claims 51-64 are newly added.

Claims 1,7-9,40,42-64 are pending and examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections Maintained - 35 USC § 102***

The rejection of claims 1,7-9,40,42, 50 and now newly added claims 51-57, and 61-64 under 35 USC § 102(b) as being anticipated by Bizak *et al* is maintained for the reasons of record. Applicant contends that the cited reference fails to teach the claimed invention. Specifically, applicant argues that the procedures performed by Bizak *et al* do not form complexes because the isolation methods used would disrupt the complexes. In particular, applicant indicates that the SDS gel electrophoresis and the sample preparation (e.g. boiling) would disrupt the  $\alpha$ 2m-peptide complex. Moreover, applicant also argues that the immunoprecipitation procedure used by Bizak *et al* would not be considered "purified" because of the presence of radiolabeled  $\alpha$ 2m, antibody, and bacterial. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Art Unit: 1643

Applicant is directed specifically to pages 81 and 82 of Bizak *et al* wherein they provide methods of purifying  $\alpha 2m$  -complexes from the conditioned media of cultured HMB-2 cells. The claims do not require a specific degree of "purity" only that they be purified. In this case, the  $\alpha 2m$ -complex has been purified from the other cellular proteins or cellular debris of the culturing process and further purified by ammonium sulfate precipitation. Moreover, the precipitation as performed by Bizak *et al* was further dissolved in PBS. As such, the composition as claimed is taught by the prior art.

Therefore, the rejection of claims under 35 USC 102(b) as being anticipated is maintained for the reasons of record.

### ***Conclusion***

Claims 1,7,9,40,42,50-57, and 61-64 are not allowed. Claims 43-49 and 58-60 appear to be free of the prior art.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1643

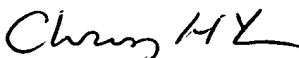
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher Yaen  
Art Unit 1643  
October 25, 2006

  
CHRISTOPHER H. YAEN  
PRIMARY EXAMINER